different techniques to deal with missing data was compared. **METHODS:** The analysis addressed the global health status scale (QL range [1;100]) of QLQ-C30, the EQ-5D utility index (Utility range [0;1]) and Visual Analysis Scale (VAS range [0;100]). Five multiple imputation (MI) techniques were carried out with two softwares (SAS, IVEware) and compared with Rubin's efficiency: Monte-Carlo Markov Chain (MCMC), Expectation-Maximization (EM), Regression (REG), Propensity score (PROP) and Sequential regression (SEQ), using 5 simulations per technique. **RESULTS:** Changes significance varied depending on the imputation technique. At baseline, mean scores were: QL 0.73, EQ-5D index 63.4, and VAS 68. For QL score, the change estimations were (mean [95%CI]): –1.699 [–3.322; –0.076] (MCMC), –1.558 [–3.132; 0.015] (EM), –1.795 [–3.449; –0.141] (REG), –1.197 [–3.067, 0.673] (PROP), –0.895 [–5.622; 3.832] (SEQ). For EQ-5D index, estimations were: –0.020 [–0.042; 0.003] (MCMC), –0.018 [–0.043; 0.007] (EM), –0.018 [–0.034; –0.002] (REG), –0.015 [–0.045; 0.014] (PROP), –0.010 [–0.049; 0.030] (SEQ). VAS changes varied from 0.019 (SEQ) to 0.791 (PROP), no change estimation was significant. Rubin's efficiency was comprised between 88.32% and 94.43% depending on score and technique. **CONCLUSIONS:** Results have to be carefully interpreted since they vary according to the MI method. SEQ is the only method not assuming a normal distribution of the data and consequently displays large confidence intervals. Nevertheless, multiple imputation is told to be robust to normality. A sensitivity analysis is advised in order to compare the different results.

PCN110

STATISTICAL METHODOLOGY IS CRUCIAL IN PROGNOSTIC FACTOR ANALYSIS OF HEALTH-RELATED QUALITY OF LIFE

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OBJECTIVES: Whilst a number of systematic reviews (e.g. Gotay et al in press) have been analyzing prognostic value of patient-reported outcomes (PROs), including HRQOL, few have focused on the statistical methods used. In this study, we reviewed the statistical methods employed and proposed robust statistical analysis for future PROs studies predicting survival of cancer patients. **METHODS:** A total of 49 English articles were selected from published reviews, conference abstracts, Medline (1990–2008), various databases and discussions with colleagues and reviewed during June to December 2007. Each article was systematically examined for a key set of factors such as design issues, selection of HRQOL factors, control for clinical factors along with a detailed extraction of the statistical methods used for analyzing HRQOL data. Once compiled, we identified good practice and recommended approaches for future research. **RESULTS:** Most HRQOL prognostic factor analyses, often within clinical trials, are not defined in protocols. In addition, a detailed description of the statistical methodology and reporting of the HRQOL results was often lacking in publications. Information regarding sample size, handling missing data and the verification of the model assumptions varied considerably. Preselection of HRQOL factors was not always done. A large number of HRQOL factors increases the risk of selecting a factor by chance and model over fitting. In the model building strategy, several approaches controlled for clinical factors in the analysis, others allowed clinical factors replacement with (perhaps slightly) more prognostic HRQOL factors. Model validation was reported in nine studies. Measures of predictive accuracy were computed in only seven studies. **CONCLUSIONS:** Undertaking HRQOL prognostic factor analysis is a challenge. The priority is validation and careful use of techniques and providing proof that the addition of HRQOL indicators significantly increases the prediction of survival in cancer patients. We hope our work will highlight these opportunities.

DIABETES/ENDOCRINE DISORDERS— Clinical Outcomes Studies

PDB1

THE IMPACT OF INSULIN DETEMIR COMPARED TO NEUTRAL PROTAMINE HAGEDORN INSULIN ON LONG-TERM DIABETES-RELATED COMPLICATIONS: A MODELING ANALYSIS IN TYPE 1 DIABETES PATIENTS IN BELGIUM, FRANCE, GERMANY, ITALY AND SPAIN

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OBJECTIVES: The aim of this analysis was to evaluate the time to onset and long-term cumulative incidence of diabetes-related complications in type 1 diabetes patients receiving either insulin detemir or Neutral Protamine Hagedorn (NPH) insulin in combination with mealtime insulin aspart in five countries (Belgium, France, Germany, Italy and Spain). **METHODS:** A published and validated computer simulation model of diabetes (CORE Diabetes Model) was used to make long-term projections of clinical outcomes, based on patient characteristics and treatment effects from a 2-year, multi-national, open-label, randomized, controlled trial. In the trial, insulin detemir was associated with significant improvements in glycemic control after 24 months (HbA1c 7.36% versus 7.58%, mean difference –0.22%, P = 0.022) and major hypoglycemic events (69% risk reduction, P = 0.001) versus NPH. Patients treated with detemir gained less weight (1.7 versus 2.7 kg, P = 0.024). Events were projected for a time horizon of 50 years. **RESULTS:** Basal-bolus therapy with insulin detemir was projected to improve mean life expectancy by 0.09 years (12.80 versus 12.71 years) versus NPH in Germany. Similar benefits were observed in the other countries (Belgium + 0.14, France + 0.13, Italy + 0.15 and Spain + 0.07 years). The time to onset of any diabetes-related complication was delayed by 0.08 years in the detemir arm (1.18 versus 1.10 years). Time to onset and cumulative incidence (CI) of diabetic eye and renal disease, neuropathy and amputations were generally decreased for detemir-based therapy, with greatest benefits observed in renal disease. The CIs of heart failure, angina and stroke were slightly raised in the detemir-based treatment arm as overall survival was increased, exposing these patients to a longer ongoing risk of these events. **CONCLUSIONS:** The modelling analysis suggests that insulin detemir is likely to improve life expectancy, delay the onset of and reduce the cumulative incidence of most diabetes related complications in type 1 diabetes patients.

PDB2

IMPROVED GLYCAEMIC CONTROL BY SWITCHING FROM INSULIN NPH TO INSULIN GLARGINE: A RETROSPECTIVE OBSERVATIONAL STUDY

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OBJECTIVES: This study investigated the effect on glycaemic control of switching from a NPH-based regimen to a glargine-based regimen in 701 patients with type 1 (T1) (n = 304) or type 2 (T2) (n = 397) diabetes, using unselected primary care data. **METHODS:** Data for this retrospective observational study were